DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

DEC 19 2012

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

December 17, 2012

Mr. Gregory Conigliaro
Owner
Ameridose LLC
201 Flanders Rd
Westborough, Massachusetts 01581

Recall Numbers: D-054-2013 and D-055-2013

Dear Mr. Conigliaro:

The U.S. Food and Drug Administration agrees with your decision to recall all sterile and non sterile drug products manufactured at your facility due to lack of assurance of sterility and significant GMP's that could impact product quality.

We have reviewed your actions and conclude that they meet the formal definition of a firm initiated recall. This is significant, as your actions are an alternative to an FDA legal action to remove your products from the market. The recalls will be reported in an issue of the FDA Weekly Enforcement Report.

Recall Numbers have been assigned as follows:

D-054-2013
All Sterile Products manufactured by Ameridose LLC, Westborough, MA

D-055-2013
All Non-Sterile Products manufactured by Ameridose LLC, Westborough, MA

A complete listing of the products recalled were identified in your recall strategy and posted to your firm's website: www.ameridose.com.

The recalls have been classified as Class II recalls. A Class II recall is defined as a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Our evaluation indicates the "Depth of Recall" should be conducted to the medical facility level. Effectiveness checks are actions taken by your firm to verify that consignees at the recall level (Depth of Recall) have received notification and have taken appropriate action. Level A effectiveness has been assigned, as your recall strategy appears to meet this requirement.

We request that you submit monthly status reports until your recalls are completed. The status reports should contain the information outlined in Section 7.53(b)(1-6) of the Recall Enforcement Policy.

At the conclusion of your recalls, FDA will request any available documentation verifying that your accounts were contacted and the necessary corrections were made. We request that this district office be notified prior to the initiation of reconditioning or destruction of the recalled product, so such action may be supervised by an FDA Investigator.

If your firm has completed the recalls, you may request termination of the recalls by submitting the attached Recall/Termination Status Report Form.

The status reports and Recall/Termination Status Report Form should be submitted to:

Susan E. Liner, Recall Coordinator
U.S. Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180-2542
(781) 587-7481

Our judgement regarding the effectiveness of your recalls will be based upon your implementation of the enclosed recall guidelines. Your cooperation in this matter is important for the protection of the public.

Sincerely,

Mutahar S. Shamsi
Director
New England District

Enclosure

Cc: Mr. Paul Cirel
Collora LLP
100 High Street
Boston, MA 02110-2321

RECALL/TERMINATION STATUS REPORT FORM

1. FIRM: Ameridose LLC
   201 Flanders Rd
   Westborough, Massachusetts 01581

2. RECALL NUMBER(S): D-054-2013 and D-055-2013

3. PRODUCT RECALLED:
   D-054-2013
   All Sterile Products manufactured by Ameridose LLC, Westborough, MA

   D-055-2013
   All Non-Sterile Products manufactured by Ameridose LLC, Westborough, MA

4. QUANTITY MANUFACTURED:

   QUANTITY DISTRIBUTED:

   QUANTITY RECOVERED:

5. DISPOSITION OF RETURNS AND/OR HELD STOCK:

   WHEN:

   WHERE:

   HOW:

6. DATE RECALL COMPLETED:

7. (A) NUMBER OF CONSIGNEES NOTIFIED:

   (Breakdown by type of consignee, if available)

   DOMESTIC

   INTERNATIONAL

   DATE OF ORIGINAL NOTIFICATION:
   METHOD OF NOTIFICATION:

8. NUMBER OF CONSIGNEES RESPONDING TO RECALL NOTIFICATION:

   DOMESTIC

   INTERNATIONAL

9. NUMBER OF CONSIGNEES NON-RESPONDING:

FOLLOW-UP TO NON-RESPONDING CONSIGNEES:

10. NUMBER AND RESULTS OF EFFECTIVENESS CHECKS MADE BY FIRM:

NUMBER EFFECTIVE
NUMBER NON-EFFECTIVE

a) LETTER

b) TELEPHONE

c) REMARKS RE: NON-EFFECTIVE CHECKS:

11. NATURE OF PROBLEM:

12. ACTION FIRM IS TAKING TO PREVENT SIMILAR OCCURRENCES:

13. PREPARER:

NAME
TITLE
DATE